REMARKS

This Office Action Response is submitted in response to the outstanding Office Action, dated June 5, 2008. Claims 1-3, 17-19, 23-25 and 29 are presently pending in the above-identified patent application. Claims 1, 17 and 23 are herein proposed to be amended. Support for the amendments can be found, for example, on page 7, lines 3-6 and page 10, lines 6-11 and page 18, lines 23-28. No new matter is being introduced.

In the outstanding Office Action, the Examiner rejected claims 1-3 and 29 under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter, and rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Barnhill et al. (United States Patent No. 6,882,990) (hereinafter "Barnhill").

The comments of the Examiner in forming the objection and rejections are acknowledged and have been carefully considered.

FORMAL REJECTIONS

As mentioned above, the Examiner rejected claims 1-3 and 29 under 35 U.S.C. 101 because the claimed invention is allegedly directed to non-statutory subject matter. Beginning on page 2 of the Office Action, the Examiner states that

> [c]laims 1-3 and 29 are not so tied to another statutory class of invention because the method steps that are critical to the invention are "not limited to any particular apparatus or machinery...." This rejection could be overcome by amendment of the claims to require that critical limitations of the process: (1) are achieved using a particular machine, or (2) the process creates or involves a composition of matter or manufacture.

Applicant, as proposed herein, has amended independent claim 1 to include a computer-implemented method for characterizing gene expression, comprising executing, via a computer, the denoted steps. Support for the amendment can be found, for example, on page 7, lines 3-6 and page 10, lines 6-11.

As stated by the United States Court of Appeals for the Federal Circuit (*In re Bilski* (2008)), "A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." As such, Applicant respectfully asserts that, as amended, independent claim 1 recites a tie to a particular machine or apparatus, namely, a computer.

Additionally, Applicant submits that independent claim 1 recites a transformation of a particular article into a different state of thing. For example, claim 1 includes the limitations of transforming said control data, wherein transforming said control data comprises transforming a probability density distribution for said control data to a uniform probability density for said control data, using said one or more transformed phenotype values to determine one or more gene expression patterns by searching said one or more transformed phenotype values for one or more patterns, wherein searching comprises using a pattern-finding algorithm to determine the one or more gene expression patterns, characterizing gene expression of an unknown sample by using the model for the probability density function of the expression level for each of the one or

more gene expression patterns of the phenotype data to determine one or more gene expression patterns for said unknown sample and comparing said one or more gene expression patterns of said unknown sample with said one or more gene expression patterns that characterize said control data and said phenotype data to classify said unknown sample as similar to either said control data or said phenotype data or neither, and outputting said characterization to a user.

As stated by the Federal Circuit in *Bilski*, "Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible." Applicant respectfully asserts that the gene expression characterization is data that is being transformed into a "particular visual depiction of a physical object on a display" via the claimed step of outputting said characterization to a user.

Further, the Federal Circuit in *Bilski* also stated, "We further note for clarity that the electronic transformation of the data itself into a visual depiction in [*In re*] *Abele* [, 684 F.2d 902 (CCPA 1982)] was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented." Similarly, Applicant submits that independent claim 1 discloses an electronic transformation of data into a visual depiction, and as such, is patentable subject matter.

Therefore, Applicant respectfully asserts that independent claim 1, as amended, overcomes the §101 rejection. Also, Applicant further submits that by virtue of their dependence on allowable independent claim 1, claims 2-3 and 29, respectively, are directed to statutory subject matter in their own right.

Given the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-3 and 29 under 35 U.S.C. §101.

PRIOR ART REJECTIONS

As mentioned above, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Barnhill. With regard to the §103 rejections, Applicants initially note that a proper *prima facie* case of obviousness requires that the cited

references, when combined, must "teach or suggest all the claim limitations," and that there be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references or to modify the reference teachings. See MPEP §706.02(j). Applicants respectfully submit that a *prima facie* case of obviousness is not present, as will be described below.

Beginning on page 6 of the Office Action, the Examiner stated that

> [t]he Examiner stated that Barnhill does not specifically disclose transformation which includes transformation to a uniform distribution within an interval, as in claims 1, 17, 23 and 29, however, Barnhill teaches that the expansion of data may comprise applying any type of meaningful transformation to the data and that the criteria for doing so really depends upon the type of data and the knowledge sought from the data. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have utilized a transformation that included uniform distribution in order that data analysis be optimized.

Applicants submit that these explanations are conclusory statements of the sort rejected by both the Federal Circuit and the U.S. Supreme Court. *See KSR v. Teleflex*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (U.S., Apr. 30, 2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

The Examiner concedes that Barnhill does not explicitly teach transforming said control data, wherein transforming said control data comprises transforming a probability density distribution for said control data to a uniform probability density for said control data. Nonetheless, the Examiner argues that "it would have been obvious to have utilized a transformation that included uniform distribution." *See* Office Action, page 7. Applicants disagree and assert that the Examiner's basis for rejection is conclusory, and unless the Examiner can present evidence supporting this contention, the claims are not obvious in light of the cited reference.

Further, Applicants respectfully assert that the amendments to independent claims 1, 17

and 23 additionally overcome the outstanding rejection by including the limitations of generating a model for a probability density function of an expression level for each of the one or more gene expression patterns of the phenotype data, and characterizing gene expression of an unknown sample by using the model for the probability density function of the expression level for each of the one or more gene expression patterns of the phenotype data to determine one or more gene expression patterns for said unknown sample and comparing said one or more gene expression patterns of said unknown sample with said one or more gene expression patterns that characterize said control data and said phenotype data to classify said unknown sample as similar to either said control data or said phenotype data or neither. Support for the amendment can be found, for example, on page 18, lines 23-28 of the specification, wherein it is stated that

> [o]nce the statistically significant patterns are found in the phenotype set, they can be used as classifiers to build a discriminant function. This function should determine whether or not a previously unseen sample, $v = (v_1, \ldots, v_{N_\theta})$, belongs to the phenotype or the control set. To this end, a model is built for the probability density function of the expression level for each statistically significant pattern Π_i of the phenotype set.

Applicants assert that the Barnhill reference does not teach or disclose the limitations of generating and using a model for a probability density function of an expression level for each of the one or more gene expression patterns of the phenotype data. As such, Applicants respectfully submit that the presently amended claims are not rendered *prima facie* obvious by the Barnhill reference. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Also, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Given the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §103(a).

In view of the foregoing, Applicants submit that all of the pending claims, i.e., claims 1-3, 17-19, 23-25 and 29, are in condition for allowance and such favorable action is earnestly

solicited.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.

The Examiner's attention to this matter is appreciated.

Respectfully submitted,

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Michael J. Cooper
Attorney for Applicant(s)
Reg. No. 57,749
Ryan, Mason & Lewis, LLP
1300 Post Road, Suite 205
Fairfield, CT 06824
(203) 255-6560